United States
of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 105th CONGRESS, FIRST SESSION

Vol. 143 WASHINGTON, FRIDAY, SEPTEMBER 5, 1997 *No. 116*

Senate

The Senate met at 9:30 a.m. and was called to order by the President pro tempore [Mr. THURMOND].

PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

Almighty God, our motto says, ''In God we trust.'' This morning our prayer is to put that motto into practice. Each of us comes to this time of prayer with his or her own set of personal needs. You know these, Lord. We place in Your strong hands whatever holds us captive to anxiety or worry. There are people in our lives for whom we are deeply concerned. We trust You with their care.

We pray for the peace of Jerusalem. We pray for the families of the 7 people who were killed in the bombing and ask for Your special care for the 200 that are now convalescing because of injuries in the bombing. O Lord, bless that city with peace.

Thank You for freeing our minds so we can work for Your glory today—with inner calm and serenity.

Lord, You know the agenda before the Senate is filled with crucial issues. We commit them to You and ask for Your guidance.

We pray that the trust we have in You may give us greater trust in one another. Make us trustworthy as we seek Your best for our Nation. Free us of defensiveness and suspicion of those who may not share our party loyalties or our particular persuasions. Bind us together in the oneness of a shared commitment to You, a passionate patriotism, and the loyal dedication to find Your solutions for the concerns that confront and often divide us.

Bless the women and men of this Senate as they place their ultimate trust in You and are faithful to the trust placed in them by the people. Through our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader is recognized.

SCHEDULE

Mr. JEFFORDS. Mr. President, for the information of all Members, this morning, the Senate will immediately begin debate on the motion to proceed to S. 830, the FDA reform bill, with the time until 9:50 a.m. equally divided in the usual form. As previously ordered, a cloture vote on the motion to proceed to the FDA bill will occur at 9:50 a.m. Also by previous consent, if cloture is invoked, the Senate will immediately begin 8 hours of debate equally divided between Senators JEFFORDS and KENNEDY on the motion to proceed. In addition, there will be an additional 4 hours of debate on the motion to proceed remaining on Monday. As a reminder to all Members, there will be a cloture vote on the motion to proceed to the FDA reform bill at 9:50 a.m. today. I thank my colleagues for their attention.

Mr. President, how much time do we have?

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997—MOTION TO PROCEED

The PRESIDING OFFICER (Mr. COATS). Under the previous order, there will be debate until 9:50 a.m., equally divided, on S. 830. It will be a little bit less than 12 minutes.

Mr. JEFFORDS. Mr. President, I yield myself 2 minutes.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Mr. President, I salute the majority leader for moving the debate on the FDA modernization forward. We should no longer needlessly delay consideration of S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997.

S. 830 represents months of bipartisan effort to address serious shortcomings in the FDA's regulatory procedures. Two hearings were held. The measure passed the committee with a strong bipartisan 14-to-4 vote, and months of negotiations have ensued with dozens of accommodations made for Senator KENNEDY and the administration.

For almost 20 years, Congress, the General Accounting Office, and numerous advisory commissions have examined, reviewed, and made recommendations to modernize the FDA.

During 1978 and 1979, Senator KENNEDY championed legislation that would have required FDA to do some of the very same things we are requiring of it in S. 830.

In 1982, the Commission on the Federal Drug Approval Process, convened at the request of Representatives ALBERT GORE and James Scheuer, recommended simpler investigational new drug requirements. The Commission recognized that drug effectiveness could be demonstrated by one study in appropriate cases, and it urged greater use of outside expert advice and improved interactions with industry.

In 1989, the advisory committee on the FDA, on which Dr. David Kessler served, made a key recommendation. It said:

> . . . the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products.

In 1991, Vice President Quayle's Council on Competitiveness recommended that the FDA expand the use of outside reviews and advisory committees, interpret efficacy with a more appropriate standard, and enhance internal agency management.

More recently, Vice President GORE has used the President's ''reinventing Government'' initiative to improve the FDA product approval system and to eliminate outmoded FDA regulations for a variety of drugs, medical devices, and food products.

● This ''bullet'' symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.